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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,785	10/30/2003	John D. Conroy JR.	21411-0001-1	8900
26587	7590	06/29/2006	EXAMINER	
MCNEES, WALLACE & NURICK LLC 100 PINE STREET P.O. BOX 1166 HARRISBURG, PA 17108-1166			DIXON, ANNETTE FREDRICKA	
			ART UNIT	PAPER NUMBER
				3743

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/697,785	CONROY, JOHN D.
	Examiner	Art Unit
	Annette F. Dixon	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 May 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-50 is/are pending in the application.
  - 4a) Of the above claim(s) 13,20-26 and 28-50 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12,14-19 and 27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 October 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/30/03 &amp; 6/9/06</u>	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II-B, **Claims 1-19 and 27**, in the reply filed on May 26, 2006 is acknowledged. The traversal is on the ground(s) that **Claims 28-47** share a special technical features with the elected claims in the pending application and that by searching and examining these claims together would not place undue burden on the Examiner. This is not found persuasive because the Examiner respectfully disagrees. As previously stated, these inventions are distinct and therefore would place an undue burden on the Examiner to search and examine both groups of claims together. For that reason, the requirement is still deemed proper and is therefore made FINAL.
2. Claims 20-26 and 28-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups I-A, I-B, and II-A, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 26, 2006.
3. It should also be noted that Applicant has cancelled **Claims 13 and 24** in response to the restriction requirement filed on May 26, 2006.

### *Double Patenting*

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

*Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 1-50 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-50 of copending Application No. 10/419672. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

#### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1, 2, 4, and 19** rejected under 35 U.S.C. 102(b) as being anticipated by Mondry (5,682,877).

8. **As to Claim 1**, Mondry discloses a system for avoiding hypoxemia comprising an air source (368), a microprocessor (364) and a first sensor (362) to measure a physiological characteristic of the patient, wherein the microprocessor (364) determines the risk of hypoxemia related to predetermined values and creates a response to the physiological characteristic. (Please see Figure 9).

9. **As to Claim 2**, Mondry discloses the first sensor (362) to be a pulse oximeter and thus a sensor that detects the oxygen red cell saturation level of a patient. (Please see Figure 9).

10. **As to Claim 4**, Mondry discloses the system to be portable. (Please see Column 2, Lines 24-28).

11. **As to Claim 19**, Mondry discloses a system for avoiding hypoxemia that detects a first time reference and if the first time reference is exceeded by the second time reference emergency procedures are initiated. (Please see Column 4, Line 51 thru Column 5, Line 14).

***Claim Rejections - 35 USC § 102 or 35 USC § 103***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. **Claim 15** is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mondry (5,682,877).

16. **As to Claim 15**, Mondry discloses a system for avoiding hypoxemia wherein the microprocessor is remote from the subject. As shown in Figure 9, the attachment of the device to the patient is via the patient's foot. Therefore it would have been obvious if not inherent for the device to be connected to the patient's foot via a wire for the purpose of attempting not to disturb the natural movement of the patient.

#### ***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mondry (5,682,877).

20. **As to Claim 10**, Mondry discloses the system to be portable. (Please see Column 2, Lines 24-28). Yet fails to expressly disclose the configuration of the device to be in one single unit. At the time the invention was made, the compact and portable design of devices for emergency use was well known for the purpose of providing efficient patient care. Therefore, it would have been obvious to one having ordinary skill in the art to design a system into a portable compact single unit as the Applicant has done. Moreover, Applicant has not asserted that the specific structural design of the system to avoid hypoxemia recited provides a particular advantage, solves a stated problem or serves a particular purpose different from that of providing a compact unit capable of aiding emergency personnel in providing fast and efficient patient care, thus the use of this compact unit lacks criticality in its design.

21. **Claims 3, 5, 6, 9, and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mondry (5,682,877) in view of Tripp Jr. et al. (US H1039).

22. **As to Claim 3**, Mondry discloses a system for avoiding hypoxemia that uses a baseline value to determine whether action is required by the doctor to assist the patient in additional oxygen ventilation; however, Mondry fails to teach the predetermined value for the oxygen red cell saturation level to be about 91 percent. However, the disclosed oxygen saturation level was known at the time the invention was made. Specifically Tripp teaches the effects of oxygen saturation depletion in patients and a desire to

maintain oxygen saturation levels between 86 percent and 95 percent, if not higher, to avoid the distress caused by oxygen depletion. (Please see Column 10, Lines 33-58). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify system of Mondry to operate at values around 91 percent because it is well known in the art, as taught by Tripp, as a point in which the effects of oxygen depletion can be corrected prior to loss of cognitive mental ability or loss of consciousness.

23. **As to Claim 5**, Mondry discloses a system for avoiding hypoxemia that is portable for the purpose of “allowing the treatment of patients outside the traditional hospital setting” (Please see Column 2, Lines 24-28). Yet Mondry fails to expressly disclose the use of the device in an aircraft. However the use of a system for avoiding hypoxemia was well known at the time the invention was made. Specifically Tripp discloses a system that is used in aircraft for the purpose of detecting potential periods of blackout by the aircraft operator due to instances of oxygen depletion. (Please see Abstract). Therefore, it would have been obvious, if not inherent, to one having ordinary skill in the art at the time the invention was made to modify the system of Mondry for use in an aircraft as taught by Tripp for the purpose of protecting the physiological well-being of the aircraft operator during flight.

24. Further, Examiner notes that Applicant has essentially claimed a statement of intended use. Specifically, in **Claim 5**, Applicant recites “for use in an aircraft.” The system of Mondry as modified by Tripp discloses an apparatus in which the claimed functional limitations can inherently be performed since the system of Mondry as

modified by Tripp is fully capable of being used in an aircraft. Thus, this recitation is a statement of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may not be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art of record in terms of structure rather than function alone. Please see MPEP §2114.

25. **As to Claim 6**, Mondry discloses a system for avoiding hypoxemia that detects a first time reference and if the first time reference is exceeded by the second time reference emergency procedures are initiated. (Please see Column 4, Line 51 thru Column 5, Line 14).

26. **As to Claim 9**, Mondry discloses a system comprising all the limitations recited in **Claim 9**, with the exception of the system to be used in an aircraft having an under pressurized cabin. However, the use of a system to avoid hypoxemia in an under pressurized cabin was well known at the time the invention was made. Specifically Tripp discloses a system that is used in high-performance tactical aircraft. As well known, the cabin pressures in tactical aircrafts decreases in relation to increases in altitude. The system of Tripp is to be used by the aircraft operator for the purpose of detecting the physiological well-being and detecting potential periods of blackout as a result of oxygen depletion. (Please see Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Mondry for use in an aircraft having an under pressurized cabin as

taught by Tripp for the purpose of protecting the aircraft operator from the negative effects of oxygen depletion.

27. Further, Examiner notes that Applicant has essential claimed a statement of intended use. Specifically, in **Claim 9**, Applicant recites "for use in an aircraft having an under pressurized cabin." The system of Mondry as modified by Tripp disclose an apparatus in which the claimed functional limitations can inherently be performed since the system of Mondry as modified by Tripp is fully capable of being used in an aircraft. Thus, this recitation is a statement of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may not be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art of record in terms of structure rather than function alone. Please see MPEP §2114.

28. **As to Claim 27**, Mondry discloses a system for avoiding hypoxemia comprising an air source (368), a microprocessor (364) and a first sensor (362) to measure a physiological characteristic of the patient, wherein the microprocessor (364) determines the risk of hypoxemia related to predetermined values and creates a response to the physiological characteristic. (Please see Figure 9). Inherently the first sensor (362) is a pulse oximeter and thus a sensor that detects the oxygen red cell saturation level of a patient. Further, Mondry discloses a system for avoiding hypoxemia that uses a baseline value to determine whether action is required by the doctor to assist the patient in additional oxygen ventilation; however, Mondry fails to teach the predetermined value for the oxygen red cell saturation level to be about 91 percent. However, the disclosed

oxygen saturation level was known at the time the invention was made. Specifically Tripp teaches the effects of oxygen saturation depletion in patients and a desire to maintain oxygen saturation levels between 86 percent and 95 percent, if not higher, to avoid the distress caused by oxygen depletion. (Please see Column 10, Lines 33-58). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify system of Mondry to operate at values around 91 percent because it is well known in the art, as taught by Tripp, as a point in which the effects of oxygen depletion can be corrected prior to loss of cognitive mental ability or loss of consciousness.

29. **Claims 17 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mondry (5,682,877) in view of Jones et al. (6,117,073).

30. **As to Claims 17 and 18**, Mondry discloses a system comprising all the limitations recited in **Claims 17 and 18**, with the exception of a warning device for providing a warning to the user. However, at the time the invention was made it was well known to provide have a device that provides a warning signal to a user. Specifically, Jones discloses an audio and visual signal that is sent to the user when oxygen saturation levels have depleted for the purpose of advising the user to take action to increase oxygen saturation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Mondry to include the audio device of Jones for the purpose of bringing to the attention of the user and surrounding persons of potentially hypoxemia condition.

31. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mondry (5,682,877) in view of Tripp Jr. et al. (US H1039), and further in view of Jones et al. (6,117,073).

32. **As to Claim 7**, Mondry discloses a system for avoiding hypoxemia that is portable for the purpose of “allowing the treatment of patients outside the traditional hospital setting” (Please see Column 2, Lines 24-28). Yet Mondry fails to expressly disclose the use of the device in an aircraft and the transmission of an emergency message to an airport tower. Regarding the expressed disclosure of the device to be used in an aircraft, the use of a system for avoiding hypoxemia in an aircraft was well known at the time the invention was made. Specifically Tripp teaches a system that is used in aircraft for the purpose of detecting potential periods of blackout by the aircraft operator due to instances of oxygen depletion. (Please see Abstract). Regarding the transmission of an emergency message, the use of a system to clinically diagnose a patient and transmit a signal to a dispatch unit was well known at the time the invention was made. Specifically Jones teaches a medical database system, which acquires and stores information about the patient. Further, this information is transmitted to a dispatch unit, which determines the care required for the patient. (Please see Column 4, Line 47 thru Column 5, Line 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Mondry for use in an aircraft and to send an emergency signal to a dispatch unit as taught by Tripp and Jones, respectively, for the purpose of protecting the physiological

well-being of the aircraft operator during flight and creating an efficient network to assist in patient care.

33. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mondry (5,682,877) in view of Tripp Jr. et al. (US H1039), and further in view of Richardson (5,372,134).

34. **As to Claim 8**, Mondry discloses a system for avoiding hypoxemia that is portable for the purpose of "allowing the treatment of patients outside the traditional hospital setting" (Please see Column 2, Lines 24-28). Yet Mondry fails to expressly disclose the use of the device in aircraft and emergency procedures to include decreasing the aircraft altitude. Regarding the expressed disclosure of the device to be used in an aircraft, the use of a system for avoiding hypoxemia in an aircraft was well known at the time the invention was made. Specifically Tripp teaches a system that is used in aircraft for the purpose of detecting potential periods of blackout by the aircraft operator due to instances of oxygen depletion. (Please see Abstract). Regarding the emergency procedures, the use of a system to disclose emergency procedures to including the decreased altitude of an aircraft were well known at the time the invention was made. Specifically Richardson teaches an aviation hypoxia monitor wherein a signal is sent to a "pilot to alert the patient to reduce his altitude or provide additional oxygen for the cockpit area" for the purpose of avoiding the troubles associated with oxygen depletion (Please see Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system

of Mondry for use in an aircraft and to send an emergency signal informing the pilot to reduce altitude as taught by Tripp and Richardson, respectively, for the purpose of protecting the physiological well-being of the aircraft operator during flight.

35. **Claims 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mondry (5,682,877) in view of Zysko (6,452,510).

36. **As to Claims 11 and 12**, Mondry discloses a system for avoiding hypoxemia that is portable for the purpose of "allowing the treatment of patients outside the traditional hospital setting" (Please see Column 2, Lines 24-28). Yet fails to expressly disclose a second sensor to measure the atmospheric pressure ambient to the patient. However the use of a device for the measurement of ambient atmospheric pressure was well known at the time the invention was made. Specifically Zysko teaches the use of a device for the measurement of ambient atmospheric pressure in an airplane cabin for the purpose of determining the concentrations and other ambient conditions of the airplane cabin for the purpose of warning the user of low air pressure in the cabin which may result in incapacitation and damage to the nervous system and measures the pressure altitude in mean sea level. (Please see Column 1, Lines 25-40). Therefore, it would have been obvious to one having ordinary skill in the art to modify the teachings of Mondry to include a sensor for monitoring ambient atmospheric pressures, as taught by Zysko, for providing a warning to the user of potential situations of hypoxia.

37. **Claims 14 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mondry (5,682,877) in view of Zysko (6,452,510), and further in view of Rapoport et al. (6,488,634).

38. **As to Claims 14 and 16**, the system of Mondry as modified by Zysko is discussed above yet fails to teach a physiological characteristic and atmospheric pressure on a storage device, transmitted to the microprocessor, and is compared to atmospheric environment of the patient. However, at the time the invention was made, the aforementioned device was well known. Specifically, Rapoport discloses an apparatus where in a patient is connected to a pulse oximeter and a pressure sensor. Prior to using the device, the patient's ambient pressure is measured and stored on the microprocessor (100). When the device is in use, additional values of the patient's airway pressures are monitored and analyzed for the purpose of determining if the patient is receiving the proper care. (Please see Figure 19 and Columns 13 and 14). As shown in Figure 19, the storage device is remote from the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the device of Mondy as modified by Zysko to further include the storage device as taught by Rapoport to provide an additional means of data to determine what treatment is needed during respiratory events.

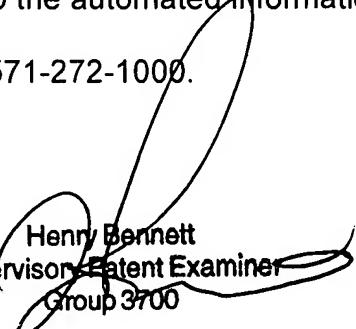
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
AFD  
June 21, 2006

  
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